



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

January 23, 2024

Michael Lau
Chief Executive Officer
Anbio Biotechnology
Friedrich-Ebert-Anlage 49, 60308
Frankfurt am Main
Germany

Re: Anbio Biotechnology
Draft Registration Statement on Form F-1
Submitted December 27, 2023
CIK No. 0001982708

Dear Michael Lau:

We have reviewed your draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1 Submitted December 27, 2023

Cover Page

1. With respect to CVC Investment and Northwestern Investment, please provide us with your analysis as to whether these shareholders are acting as a "group" as determined by Exchange Act Rule 13d-5(b)(1). We note in this regard your disclosure under the risk factor entitled "Our corporate actions will be substantially controlled by our shareholders, CVC Investment and Northwestern Investment, which will have the ability to control or exert significant influence over important corporate matters that require approval of shareholders." If these shareholders will be acting as a group or otherwise controlling the Company, please tell us whether you will be a controlled company under the Nasdaq rules upon the completion of your offering. If you will be a controlled company, please include appropriate disclosure on the prospectus cover page and in the prospectus summary and provide risk factor disclosure of this status and disclose the corporate governance

exemptions available to a controlled company. To the extent you will be a controlled company, the cover page and prospectus summary disclosure should include the identity of your controlling shareholders, the amount of voting power the controlling shareholders will own following the completion of the offering, and whether you intend to rely on any exemptions from the corporate governance requirements that are available to controlled companies.

2. Please revise the prospectus cover page to include a cross reference to the risk factors section, including the page number where it appears in the prospectus. Refer to Item 1 of Form F-1 and Item 501(b)(5) of Regulation S-K.

Table of Contents, page i

3. We note your statement below the Table of Contents that you have not independently verified the statistical data, industry data, forecasts, and market research used in the prospectus. This statement may imply an inappropriate disclaimer of responsibility with respect to such information. Please either delete this statement or specifically state that you are liable for such information.

Prospectus Summary

Our Competitive Strengths, page 1

4. We note from your disclosure on pages F-10 and F-24 that a significant amount of your revenues has been derived from the European Union and from your disclosure on page 64 that you have significant customer concentration. Please balance your disclosure regarding a diversified global customer portfolio in this regard. Also revise your disclosure under "Diversified Global Customer Portfolio" on page 50 as appropriate.

Implications of Being an "Emerging Growth Company", page 5

5. We note your disclosure in the last bullet point of the first paragraph that you will not be required to conduct an evaluation of your internal control over financial reporting. Please revise this so that it is consistent with your disclosure on page 18 that Section 404 of the Sarbanes-Oxley Act will require you to include a report from management on the effectiveness of your internal control over financial reporting in your annual report on Form 20-F beginning with your annual report for the fiscal year ending December 31, 2023.

Risk Factors

There can be no assurance that we will not be a passive foreign investment company, or PFIC..., page 24

6. We note your disclosure on page 99 that you do not intend to provide information necessary for U.S. holders to make qualified electing fund elections which, if available, you disclose would result in tax treatment different from (and generally less adverse than) the general tax treatment for PFICs that you describe. In this risk factor, disclose that you

do not intend to provide the information that would enable investors to make a qualified electing fund election that could mitigate the adverse U.S. federal income tax consequences should you be classified as a PFIC.

Use of Proceeds, page 29

7. Please revise your disclosure in this section to address the following:

- Clarify what is meant by “global market.” For example, it is unclear whether you intend to use the proceeds from this offering to expand into every market or markets in specific countries, regions, etc.
- Clarify how far into the development process you estimate the proceeds from the offering will enable you to reach. For example, you disclose that you will use proceeds to seek regulatory approval in the global market, including relevant clinical studies and trial testing, and to research and develop new products, commercialize existing products, and validate quality assurance, but it is unclear whether you expect the proceeds will be sufficient to move from research and development all the way through the approval process and commercialization.
- Identify each program, product, or product candidate you plan to fund with the proceeds from the offering and the dollar amount you intend to allocate to each program, product, or product candidate in each of the uses described in the first three line items of the table. For example, disclose the clinical studies and trial testing that will be funded with proceeds from the offering, as well as which existing products you intend to commercialize with proceeds from the offering.
- Disclose whether the allocated proceeds will be sufficient to complete the actions described in the table or whether you will require additional funds to accomplish the specified purposes for which the proceeds are intended to be used.
- Ensure consistency between the disclosures in this section and the disclosures on page 7 referring to the expansion of your research and development pipeline, advancing customer service, and strengthening sales operations.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Factors Affecting Our Operating Results

Increases in the Price of Life Sciences Reagents and Consumables May Harm Our Profitability, page 35

8. We note your disclosure that you ask your suppliers not to increase prices unilaterally without giving you a 12-month advance notice due to the fluctuation in foreign exchange. Please revise your disclosure to clarify whether your suppliers generally honor such request to the extent material and whether you enter into contractual agreements with your suppliers regarding the same. In addition, if your suppliers are not obligated to provide the requested advance notice to you, please revise your disclosure to state that fact.

Impact of COVID-19, page 35

9. We note your disclosure in the first sentence that you are a fast-growing biomedical diagnostic company and that you are confident you will offer your mature non-COVID-19 IVD products to the global market as soon as possible. Please disclose the measure by which you characterize the Company as “fast-growing.” In this regard, we note the significant decrease in revenue during the first six months of 2023. In addition, please clarify which mature non-COVID-19 IVD products you intend to offer to the global market, what is meant by “global market,” and your anticipated timeline for introducing these products to the global market. In this regard, the breadth of your intended reach into the “global market” is unclear and your reference to offering certain products “as soon as possible” is ambiguous as to how soon the products could actually be offered into the market.
10. We note your disclosure in the second paragraph that, when the transition period for the IVDR 2017/746 Directive ends, your CE marked products may need to be recertified under the IVDR 2017/746 Directive before they can legally be sold in the EU. Please disclose when the transition period is expected to end, which of your products may, or will, require certification, the status and anticipated timeline for recertification of your products, and the potential impact on the Company resulting from any delay in, or failure to receive, recertification.

Results of Operations

Other Income, net, page 38

11. Please disclose what sample income, noted here, and customized package design service, noted on page 39, relates to, and disclose if you will continue with these lines of business and provide your accounting policy for recognizing such revenue in your notes to the financial statements.

Research and Development Expenses, page 39

12. Refer to your disclosure beginning on page 61 relating to your research and development activities. Please revise your disclosure here to describe the types of research and development costs incurred. In addition, revise your disclosure on page F-25 to include your research and development accounting policy which is noted within your discussion of Operating Expenses in Note 2, Summary of Significant Accounting Policies. Refer to Item 5.C of Form 20-F.

Critical Accounting Estimates, page 41

13. Please explain why you appear to include separate discussions of Critical Accounting Estimates and Critical Accounting Policies or revise. Refer to Item 5.E of Form 20-F.
14. Critical accounting estimates are those estimates made in accordance with generally accepted accounting principles that involve a significant level of estimation uncertainty

and have had or are reasonably likely to have a material impact on your financial condition or results of operations. Your disclosure should provide qualitative and quantitative information necessary to understand the estimation uncertainty and the impact the critical accounting estimate has had or is reasonably likely to have on your financial condition or results of operations and should include why each critical accounting estimate is subject to uncertainty and how much each estimate and/or assumption has changed over a relevant period, and the sensitivity of the reported amount to the methods, assumptions and estimates underlying its calculation. Refer to Item 5.E of Form 20-F.

Specifically, please revise to explain why each critical accounting estimate (Revenue Recognition, Leases, Fair Value Measurement, Income Taxes and Estimated Allowance for Accounts Receivable) is subject to uncertainty and how much each estimate and/or assumption has changed over a relevant period, and the sensitivity of the reported amounts to the material methods, assumptions and estimates underlying its calculation. For example, you state that there was no provision for doubtful accounts as of June 30, 2023, December 31, 2022 and 2021. Please revise your disclosure to more fully describe the judgments, methods, inputs, and assumptions involved in your determination.

Business, page 48

15. Please revise your disclosures in this section and throughout the prospectus as appropriate to clarify the current status of your various programs, solutions, products, and product candidates. For example, please clarify their current stage of development and/or commercialization; which of them require regulatory approval and where they are in the approval process; and your timelines and anticipated plans for marketing, distributing, and otherwise commercializing the same. In this regard, we note references in this section and elsewhere in the prospectus to your extensive portfolio of IVD products designed to cater to diverse diagnostic needs, your comprehensive range of products encompassing solutions for various applications, your advanced diagnostic capabilities, your versatile range of products, and other similar characterizations that imply you have a broad product line available. However, we also note your disclosure on page 53 that your product lineup primarily features rapid antigen tests for COVID-19, as well as your disclosures throughout the prospectus that 99% of your revenues were generated from sales of your SARS-CoV-2 and SARS-CoV-2/Flu A/Flu B Antigen Rapid Test Kit.
16. We note your disclosure that you developed and distributed a comprehensive range of robust solutions to meet the growing demand in the POCT and OTC markets. Given your limited operating history, your disclosure on page 61 that you only incurred nominal research and development expenses in 2022, and the broad product lineup you discuss throughout the prospectus, please briefly describe the research and development activities you have conducted to date. To the extent that you acquired products and solutions from third parties, please briefly describe that aspect of your business strategy.

Our Products

Types of Products, page 54

17. Please revise the table to clearly identify which products, if any, require regulatory approvals; which regulatory approvals, if any, the products have received; which products are commercially available and/or ready for commercialization; and your plans and expectations for the same. In this regard, we note general disclosure on page 51 that certain of your non-COVID-19 related products are registered for commercialization in the EU under CE Mark authority and that you plan to commercialize non-COVID-19 related products via distributors for the fiscal year ending December 31, 2023 and beyond. For any products not yet commercially available or ready for commercialization, please identify where the product is in the development process.

Clinical Results, page 60

18. We note references in this section to conclusions related to the data generated from your studies. For example, you disclose conclusions related to the suitability of your SARS-CoV-2 Antigen Rapid Test and characterize the results as exhibiting “excellent” sensitivity and specificity. In addition, you disclose that a study concluded that your SARS-CoV-2/Influenza A/B Antigen Rapid Test is “accurate, sensitive, specific, and user-friendly, requiring minimal training, and is suitable for point-of-care and home use to detect COVID-19, Influenza A, and Influenza B.” While we do not object to your disclosure of objective data resulting from the trials, please delete any conclusions you drew from such data as inappropriate given the regulatory authorities’ role in the approval process for medical devices. Please make similar revisions throughout the registration statement as appropriate.

Our Suppliers, page 63

19. We note your supplier concentration for the periods presented. Please disclose whether you have contracts with your suppliers and the material terms of such contracts. Please file any material contract as an exhibit to your registration statement or provide us with an analysis as to why that would not be appropriate.

Intellectual Property, page 64

20. Please disclose whether you own or license your intellectual property. In addition, please disclose the specific products or product groups to which your patent and trademark applications relate.

Employees, page 66

21. Please disclose the breakdown of employees by main category of activity and geographic location. Refer to Item 4.a of Form F-1 and Item 6.D in Part I of Form 20-F. Also, given that you appear to have only incurred research and development expenses in 2022, please

tell us how to reconcile your disclosure that around 15% of your staff members are involved with research and development with the expenses shown on the financial statements included in your filing.

Management, page 71

22. We note your disclosure that Michael Lau has served as a Vice President of Global Head of GMP Operations and Diagnostics for Genscript Biotech Corp. since July 2017 and that he is responsible for management of a business development and sales team for 28 states in the United States and South America. Please revise your disclosure to clarify whether Mr. Lau continues to hold this position and, if not, when he left this position. If Mr. Lau continues to hold this position, please:
- disclose how Mr. Lau's time and attention is allocated between the Company and Genscript and whether the Company is party to any arrangements regarding the same;
 - disclose, as appropriate in the prospectus, any competing interests between the Company and Genscript and what measures, if any, the Company has taken to protect its confidential information and its intellectual property from Genscript; and
 - include risk factor disclosure in the "Risk Factors" section of the prospectus regarding any potential conflicts of interest, the diversion of Mr. Lau's time and attention away from the Company, and any other material risks associated with Mr. Lau's dual roles.

To the extent material, please provide similar disclosures regarding Richard Chen's dual role as Chief Financial Officer of the Company and as a partner of CLC LLP, particularly as such disclosures relate to the allocation of Mr. Chen's time and attention between the Company and CLC.

23. Please disclose any arrangement or understanding with major shareholders or others pursuant to which any of the executive officers were selected as a member of senior management or Mr. Xu was selected as a director. Refer to Item 4.a of Form F-1 and Item 6.A.5 of Part I of Form 20-F.

Board of Directors, page 72

24. We note your disclosure that "[a] director may exercise all the powers of the company...." Please clarify whether a single director may exercise these powers or whether the exercise of such powers requires action by the board of directors.

Executive Compensation

Agreements with Named Executive Officers, page 76

25. We note your disclosure that you "plan" to implement incentive compensation arrangements with your senior executive officers under an executive incentive compensation plan if the Company exceeds a target market cap for six consecutive months. Please disclose how the target market cap will be calculated for this purpose or

cross reference to the exhibit, if applicable, where the “Market Capitalized Target” is defined. In addition, please clarify whether you are obligated to pay the specified amounts upon achievement of the target and whether, like the payment to be made to Mr. Lau, the payments to Mr. Chen and Mr. Tian will be made in stock. Finally, please include a brief description of the executive incentive compensation plan, file a copy of the plan as an exhibit to the registration statement, and disclose here how many shares will be authorized under the plan. Refer to Item 8.a of Form F-1 and Item 601(b)(10)(iii) of Regulation S-K.

Principal Shareholders, page 77

26. Although we note your disclosure that James Howard is the sole proxy holder of the shares held by CVC Investment, and that Mark Martinez is the sole proxy holder of the shares held by Northwestern Investment, please revise your disclosure to clarify the natural person or persons who have ultimate voting control and investment control of the shares held by these entities. Also, if Messrs. Howard and Martinez were granted their proxies by other natural persons, please make that clear.

Description of Share Capital

Ordinary Share, page 79

27. We note your disclosure in the first sentence that all of your issued and outstanding Class A ordinary shares and Class B ordinary shares are fully paid and nonassessable. We note a similar statement on page 80. Please reconcile these disclosures with the statement on page II-1 of the registration statement that the consideration for the June 30, 2023 private placement of Class A ordinary shares and Class B ordinary shares has not been paid as of the date of the prospectus.

Class B Ordinary Shares, page 80

28. Please clarify how the amount of the repayment of capital on the Class B ordinary shares would be calculated. Also indicate whether the Class B ordinary shares are convertible into Class A ordinary shares and the conversion terms, if any. We also note that the Class B ordinary shares do not have any economic interest in your company. If such shares are convertible into Class A ordinary shares, please disclose any resulting impact on the Class A ordinary shareholders, including dilution, and include appropriate risk factor disclosure.

Underwriting

Underwriters' Warrants, page 101

29. Your disclosure that the underwriters' warrants will be exercisable for five years from the commencement of sales in the offering appears to be inconsistent with your disclosure that the underwriters' warrants will terminate on the third anniversary of the commencement of sales in the offering. Please revise your disclosure to clarify the term of the underwriters' warrants.

Expenses Relating to this Offering, page 107

30. Please include a line item in the table for transfer agent fees and expenses and for any premiums paid to insure directors or officers for liabilities in connection with the registration, offer or sale of the securities you are registering. Refer to Instruction to Item 9.F of Form 20-F.

Note 2- Summary of Significant Accounting Policies

Revenue Recognition, page F-23

31. Please revise your revenue recognition policy to specifically state when control is transferred (i.e. shipping point or delivery) as “generally upon contract terms” is vague.

Item 7. Recent Sales of Unregistered Securities, page II-1

32. We note that upon incorporation, the company issued 50 ordinary shares to founding shareholders, and that on June 30, 2023 the company issued Class A Ordinary Shares to "other shareholders" that were not CVC Investment or Northwestern Investment. Please name the persons or identify the class of persons to whom these securities were sold. Refer to Item 7 of Part II of Form F-1 and Item 701(b) of Regulation S-K.
33. We note that the securities disclosed in this section were sold for nominal consideration, some of which has not been paid as of the date of this prospectus, and we note no cash flows from financing activities in your consolidated statements of cash flows for the fiscal years ended December 31, 2021 and 2022. With a view towards revised disclosure, please tell us how you obtained capital to commence operations.

Signatures, page II-4

34. Please revise the signature block to identify which officer is signing in his capacity as the Company’s controller or principal accounting officer. Refer to Instructions 1 and 2 to Signatures in Form F-1.

Signature of Authorized Representative in the United States, page II-5

35. Please revise the preamble to this section as appropriate. In this regard, although it appears you intend to have a representative of Cogency Global Inc. sign the registration statement, the preamble refers to “Star Venture Investment Holding Limited.”

General

36. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Michael Lau
Anbio Biotechnology
January 23, 2024
Page 10

Please contact Sasha Parikh at 202-551-3627 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Jessica Dickerson at 202-551-8013 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: William S. Rosenstadt, Esq.